

WHAT IS CLAIMED IS:

5 1. A compressed tablet comprising: efavirenz, filler/disintegrant, superdisintegrant, binder, surfactant, diluent/compression aid, lubricant, and solvent, wherein efavirenz is about 50% by weight of the total composition of the compressed tablet.

10 2. The compressed tablet, as recited in Claim 1, wherein the filler comprises: lactose, calcium carbonate, calcium sulfate, compressible sugars, dextrates, dextrin, dextrose, calcium phosphate, kaolin, magnesium carbonate, magnesium oxide, maltodextrin mannitol, powdered cellulose, pregelatinized starch, and sucrose.

15 3. The compressed tablet, as recited in Claim 2, wherein the disintegrant and superdisintegrant comprise: alginic acid, carboxymethylcellulose calcium, carboxymethylcellulose sodium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, guar gum, magnesium aluminum silicate, methylcellulose, microcrystalline cellulose, polyacrilin potassium, powdered cellulose, pregelatinized starch, sodium alginate and starch.

20 4. The compressed tablet, as recited in Claim 3, wherein the binder comprises: acacia, alginic acid, carbomer, dextrin, ethylcellulose, gelatin, guar gum, hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, liquid glucose, magnesium aluminum silicate, maltodextrin, methylcellulose, polymethacrylates, povidone, pregelatinized starch, sodium alginate, starch, and zein.

25 5. The compressed tablet, as recited in Claim 4, wherein the surfactant comprises: sodium lauryl sulfate, docusate sodium, benzalkonium chloride, benzethonium chloride, and cetrimide.

30 6. The compressed tablet, as recited in Claim 5, wherein the filler/compression aid comprises: calcium carbonate, calcium sulfate, compressible sugars, confectioner's sugar, dextrates, dextrin, dextrose, dibasic calcium phosphate dihydrate, glyceryl palmitostearate,

hydrogenated vegetable oil (type I), kaolin, lactose, such as lactose hydrous spray dried, magnesium carbonate, magnesium oxide, maltodextrin, mannitol, polymethacrylates, potassium chloride, powdered cellulose, pregelatinized starch, sodium chloride, sorbitol, starch, sucrose, sugar spheres, talc and tribasic calcium phosphate.

7. The compressed tablet, as recited in Claim 6, wherein the lubricant comprises: calcium stearate, glyceryl monostearate, glyceryl palmitostearate, hydrogenated castor oil, hydrogenated vegetable oil, light mineral oil, magnesium stearate, mineral oil, polyethylene glycol, sodium benzoate, sodium lauryl sulfate, sodium stearyl fumarate, stearic acid, talc and zinc stearate.

8. The compressed tablet, as recited in Claim 7, wherein the solvent comprises: water, ethanol or mixtures thereof.

9. The compressed tablet, as recited in Claim 8, wherein the filler/disintegrant is a microcrystalline cellulose.

10. The compressed tablet, as recited in Claim 9, wherein the superdisintegrant is a croscarmellose sodium.

11. The compressed tablet, as recited in Claim 10, wherein the binder is a hydroxypropyl cellulose.

12. The compressed tablet, as recited in Claim 11, wherein the surfactant is a sodium lauryl sulfate.

13. The compressed tablet, as recited in Claim 12, wherein the filler/compression aid is a lactose hydrous spray dried.

14. The compressed tablet, as recited in Claim 13, wherein the lubricant is a magnesium stearate.

15. The compressed tablet, as recited in Claim 14, comprising efavirenz, microcrystalline cellulose NF, hydroxypropyl cellulose LF NF, croscarmellose sodium, sodium lauryl sulfate, lactose hydrous spray dried (EG), and magnesium stearate (EG).

5

16. The compressed tablet, as recited in Claim 15, containing about 300 mg of efavirenz, about 120 mg microcrystalline cellulose NF, about 19.2 mg hydroxypropyl cellulose LF NF, about 30 mg croscarmellose sodium, about 6 mg sodium lauryl sulfate, about 118.8 mg lactose hydrous spray dried (EG), and about 6 mg magnesium stearate (EG).

10

17. A process for the preparation of a 50 % drug loaded compressed tablet comprising the following steps:

15

(a) blending efavirenz with a filler/disintegrant, super-disintegrant, binder and surfactant;

(b) adding at least 1.1% by weight of water per weight of efavirenz to wet granulate the blended mixture to agglomerate the mixture;

20

(c) drying the granulated mixture to a moisture content of about 0% to about 10%;

(d) milling the dried mixture to granulate to a uniform size;

(e) blending the milled mixture with a filler/compression aid;

(f) lubricating the blended mixture with a lubricant; and

25

(g) compressing the lubricated mixture to a compressed tablet of the desired shape.

30

18. The process as recited in Claim 19 which comprises the additional step of film coating the compressed tablet with a film coating suspension to produce the desired film coated compressed tablet.

19. The process as recited in Claim 18 wherein the granulated mixture is dried to a moisture content of about 2% to about 5%.

20. A process for the preparation of a 50 % drug loaded film coated compressed tablet comprising the following steps:

- 5 (a) blending efavirenz with microcrystalline cellulose, sodium lauryl sulfate, hydroxypropyl cellulose and croscarmellose sodium;
- (b) adding at least 1.1 weight % water per weight of efavirenz to wet granulate the blended mixture for about 3 minutes to about 8 minutes to agglomerate the mixture;
- 10 (c) drying the granulated mixture to a moisture content of about 2% to about 5%;
- (d) milling the dried mixture to a granulate of about 250 μ to about 75 μ ;
- (e) blending the milled mixture with lactose;
- (f) lubricating the blended mixture with magnesium stearate;
- 15 (g) compressing the lubricated mixture to a compressed tablet of the desired shape; and
- (h) film coating the compressed tablet with a film coating suspension to about 1% to about 10% by weight of the weight of compressed tablet.

20 21. The process as recited Claim 20, wherein the blended mixture is wet granulated for about 6 minutes.

22. The process as recited Claim 21, wherein the film
25 coating suspension comprising hydroxypropylcellulose, hydroxypropyl methylcellulose, and titanium dioxide.

23. The process as recited Claim 22, wherein the
compressed tablet is film coated with the film coating suspension to
30 about 3.1% to about 3.3% by weight of the weight of compressed tablet.

add A4

add CS